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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,347	SOOTHILL ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-47,49-53,55-59,61,62 and 65-75* is/are pending in the application.

4a) Of the above claim(s) *44,45,49-53,55-59,61,62,65,66 and 68-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-43,46,47 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of claims 35-48, 65-67, 70, 72 and 74 with a further *election* of the bacteriophage panel consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 wherein a panel differs from said panel by any substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity, in the reply filed on February 2, 2009 is acknowledged.

Applicant argues that:

1) The Hanlon et al. reference cited by the Examiner does not impact the presently claimed invention because it focuses on the use of bacteriophage-produced alginase (a polysaccharide lyase) to breakdown *P. aeruginosa* biofilms.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, despite Applicant's assertion, the combination of a bacteriophage and an antibiotic is not the linking feature of the claims. Neither Groups II nor III requires administration or antibiotics, nor does the method of detecting *P. aeruginosa* require administration or antibiotics. The only feature that can be found in all of the groups is a bacteriophage. The Hanlon et al. reference discloses bacteriophages. Therefore, the linking technical feature has been met in the claims.

Moreover, in a short interview on January 26, 2009 the Examiner acknowledged that the restriction requirement was mailed after the second preliminary amendment was filed, but that the requirement did not address the new claims. The Examiner

initially agreed that new claims 65-67, 70, 72 and 74 would be added to Group I. Upon further consideration claims 70, 72 and 74 will be withdrawn from Group I as they are drawn to different methods that are not encompassed by the method of Group I. Newly added claims 70, 72 and 74 are drawn in part to a method of therapeutic or prophylactic treatment of a bacterial infection comprising or consisting of *P. aeruginosa* which comprises administering to a human or non-human animal a composition comprising one or more bacteriophages selected from the bacteriophage strains NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179, NCIMB 41180 and NCIMB 41181 deposited at the National Collection of Industrial and Marine Bacteria, Aberdeen, United Kingdom, and variants thereof which retain the ability to target P. aeruginosa, preferably having at least 95% nucleotide sequence identity across the whole genome compared to the genome of one of said deposited strains, together with a pharmaceutical carrier or diluent. Mean while, the elected invention of Group I, claims 35-48 and 65-67 are drawn to a method of treating a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, said one or more bacteriophages targeting bacteria of said infection and said method comprising administration of said one or more bacteriophages sequentially with one or more antibiotics, with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage preparations, or separately therefrom.

The methods, as evidenced by the claims themselves, are directed to different inventions which are not connected in design, operation, or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The requirement is still deemed proper and is therefore made FINAL.

Consequently, claims 35-47, 49-53, 55-59, 61, 62, and 65-75 are pending. Claims 44, 45, 49-53, 55-59, 61, 62, 65, 66, and 68-75 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-34, 48, 54, 60, 63 and 64 have been canceled. Claims 35-43, 46, 47 and 67 are currently under examination.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on April 18, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable codes, for example pages 2-4. Applicant is required

to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

4. Claim 46 is objected to because of the following informalities: Claim 46 depends on a non-elected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 46 is drawn to a method of treating of a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, said one or more bacteriophages targeting bacteria of said infection and said method comprising administration of said one or more bacteriophages sequentially with one or more antibiotics, with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage

preparations, or separately therefrom, wherein a panel of bacteriophages is employed consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 or a panel which differs from said panel by substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity.

Because it is not clear that cell lines possessing the properties of **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179** are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179**, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 on page 12** of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met. If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under

the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

> (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
>
> (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
>
> (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As well as a statement that removes restrictions to provide access to this strain upon granting of a patent has been made, neither in the instant Specification, nor in Applicant's Remarks.

One of the critical conditions of Deposit is defined in 37 CFR 1.808 requires that the deposit of biological material be made under two conditions: (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent. Upon making this

statement, the rejection under 35 USC 112, first paragraph will be withdrawn. This rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit. If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the **NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179** described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

6. Claims 35-43, 46, 47 and 67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant previously amended claim 35 to recite "with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage preparations, or separately therefrom". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent.

To overcome this rejection Applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

7. Claims 35-43, 46, 47 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a method of treatment of a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, said one or more bacteriophages targeting bacteria of said infection and said method comprising administration of said one or more bacteriophages sequentially with one or more antibiotics, with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage preparations, or separately therefrom, wherein a panel of

bacteriophages is employed consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 or a panel which differs from said panel by substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus of polypeptides or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention.

A representative number of species means that the species which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

The specification lacks full written description for which panel differs from bacteriophages consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 by substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity and still be effective to treat any bacterial infection characterized by biofilm formation.

The University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

Further, Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page

1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

8. Claims 46, 47 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating canine ear infections related to *P. aeruginosa* comprising administering to an animal in need thereof a bacteriophage preparation consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 (BioVet-Pa) together with one or more antibiotics, does not reasonably provide enablement for a method of treatment or prevention (i.e. prophylactic treatment), as recited in claim 42, of any bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, said one or more bacteriophages targeting bacteria of said infection and said method comprising administration of said one or more bacteriophages sequentially with one or more antibiotics, with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage preparations, or separately therefrom, wherein a panel of bacteriophages is employed consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 *or a panel which differs from said panel by substitution of any of said bacteriophages by a variant thereof which exhibits desired*

target strain specificity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the establishment of this scope of enablement rejection. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The claimed invention is directed to a method of treating or preventing (prophylactic treatment) a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, said one or more bacteriophages targeting bacteria of said infection and said method comprising administration of said one or more bacteriophages sequentially with one or more antibiotics, with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage preparations, or separately therefrom, wherein a panel of bacteriophages is employed consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 or a panel which differs from said panel by substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity.

Breadth of the claims: The claims are broadly drawn and encompass a method of treating and preventing (i.e. prophylactic treatment as recited in claim 42) any bacterial infection, which is not limited to an infection selected from infection of a skin burn or other skin wound, a lung infection, an ocular infection, a urinary infection or infection associated with a medical device or implant comprising administering any one or more bacteriophage preparations comprising any one or more bacteriophage.

Subsequent claim 46 is broad and encompasses a panel of bacteriophages consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 or a panel which differs from said panel by any substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity.

Direction or guidance presented in the specification: The specification provides enablement for a method of treating canine ear infections related to *P. aeruginosa* which comprises administering to an animal in need thereof a bacteriophage preparation consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 (BioVet-Pa) together with one or more antibiotics. However, the specification lacks enablement for a method of treating or preventing any bacterial infection comprising administering any one or more bacteriophage preparations comprising any one or more bacteriophage.

To be a prophylactic method, said method must induce a protective immune response demonstrated by challenge experiments in an acceptable animal model. The specification does not provide substantive evidence that the claimed composition is capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed method for their intended purpose of prevention. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced.

Moreover, the specification lacks enablement for treating or preventing any bacterial infection comprising administering a panel of bacteriophages consisting of

NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, NCIMB 41179 wherein a *panel differs from said panel by any substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity.* The specification is silent with regard to which bacterial infection can be treated or prevented when a patient in need thereof is administered any bacteriophage or panel of bacteriophages that differs from NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178, and NCIMB 41179 by any substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity. It is unclear which combined bacteriophage preparation comprising a plurality of bacteriophages will have the capability of infecting the same bacterial species, wherein each member of said plurality of bacteriophages have a different strain specificity, as recited in claim 37 and still retain the ability to treat or prevent any bacterial infection characterized by biofilm formation.

Moreover, the claims are drawn to any bacterial infection, which is not limited to, but can include an infection selected from infection of a skin burn or other skin wound, a lung infection, an ocular infection, a urinary infection or infection associated with a medical device or implant. Lung infections alone are caused by bacteria and viruses as well as fungi. The specification is silent with regard to how the claimed method will successfully combat, for example a viral or fungi based lung infection.

The specification is equally silent with regard to which variant of said deposited bacteriophage strain employed has at least 95% nucleotide sequence identity across its whole genome compared to the genome of the relevant deposited strain, as recited in

claim 67. There is no baseline sequence recited in claims 35, 46 or 67. The baseline sequence for any one of the six deposited bacteriophage strains are critical and essential to the practice of the invention, but has not been included in the claim(s) and is not enabled by the disclosure. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Without these baseline sequences one of skill in the art would not be able to identify which deposited bacteriophage strain has at least 95% nucleotide sequence identity across its whole genome when compared to the genome of the relevant deposited strains. The skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation.

Presence or absence of working examples: There are no working examples provided to rectify the missing information in the instant specification pertaining to the claimed variant.

Quantity of experimentation necessary: The quantity of experimentation necessary would be undue as the claims encompass a method of treating or preventing any bacterial infection comprising administering any one or more bacteriophage preparations comprising any one or more bacteriophage. Moreover, claim 46 is broad and encompasses a panel of bacteriophages consisting of NCIMB 41174, NCIMB 41175, NCIMB 41176, NCIMB 41177, NCIMB 41178 and NCIMB 41179 or a panel which differs from said panel by any substitution of any of said bacteriophages by a variant thereof which exhibits desired target strain specificity. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it

cannot be predicted from the disclosure how to make/use the claimed genus. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidence by the state of the prior art, attempting the construct and test variants of the claimed invention would constitute undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 35-38, 40, 42 and 43 are rejected under 35 U.S.C. 102(b) as anticipated by Slopek et al. (Archivum Immunologiae Et Therapiae Experimentals, 1984; 32(3): 317-35).

The rejected claims are drawn to a method of treatment of a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, said one or more bacteriophages targeting bacteria of said

infection and said method comprising administration of said one or more bacteriophages sequentially with one or more antibiotics, with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage preparations, or separately therefrom.

Slopek et al. disclose a method of treating bacterial infections including but not limited to diseases of the skin and subcutaneous tissue, conjunctivitis, otitis media, pneumonia, infections of the urinary tract, open wounds and burns (see title and page 323). Slopek et al. disclose that the method comprises phage therapy without parallel antibiotic therapy as well as parallel administration of bacteriophages and antibiotics (page 318, ¶ 3). Moreover, Slopek et al. disclose that in phage therapy the use was made of specific virulent bacteriophages and that the bacteriophages were used as moist applications on the wounds and as inhalations and as eye and nose drops (see page 318, ¶ 6). Slopek et al. disclose that bacterial infections include infections due to *Pseudomonas* (page 321, Table 7). The bacteriophages of Slopek et al. are necessarily capable of infecting the same bacterial species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slopek et al. (Archivum Immunologiae Et Therapiae Experimentals, 1984; 32(3): 317-35) as applied to claims 35-38, 40, 42 and 43 above.

The rejected claims are drawn to a method of treatment of a bacterial infection characterized by biofilm formation which comprises administering to a human or non-human animal in need thereof one or more bacteriophage preparations comprising one or more bacteriophages, said one or more bacteriophages targeting bacteria of said infection and said method comprising administration of said one or more bacteriophages sequentially with one or more antibiotics, with the proviso that said method excludes administration of a polysaccharide lyase by means of said one or more bacteriophage preparations, or separately therefrom.

Slopek et al. disclose a method of treating bacterial infections including but not limited to diseases of the skin and subcutaneous tissue, conjunctivitis, otitis media, pneumonia, infections of the urinary tract, open wounds and burns (see title and page 323). Slopek et al. disclose that the method comprises phage therapy without parallel antibiotic therapy as well as parallel administration of bacteriophages and antibiotics (page 318, ¶ 3). Moreover, Slopek et al. disclose that in phage therapy the use was made of specific virulent bacteriophages and that the bacteriophages were used as moist applications on the wounds and as inhalations and as eye and nose drops (see page 318, ¶ 6). Slopek et al. disclose that bacterial infections include infections due to *Pseudomonas* (page 321, Table 7). The bacteriophages of Slopek et al. are necessarily capable of infecting the same bacterial species.

Slopek et al. do not specially disclose *Pseudomonas aeruginosa* and does not specifically disclose that the ear infection is a canine ear infection.

It would have been obvious to one of skill in the art at the time the invention was made to have a bacterial infection caused by *Pseudomonas aeruginosa* and to treat a canine ear infection because Slopek et al. disclose bacteria from the genus *Pseudomonas* as well as bacterial infections to include ear infections. One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for treating a bacterial infection because *Pseudomonas aeruginosa* is one of the most common bacterial strains associated with canine ear infections.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645

LJT
3/9/09